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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,185	09/08/2003	Michiya Okada	501.42340CX1	8416

20457 7590 03/19/2004

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EXAMINER

VARGAS, DIXOMARA

ART UNIT	PAPER NUMBER
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2859

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,185

Applicant(s)

OKADA ET AL.

Examiner

Dixomara Vargas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the gradient magnetic field coil and a high frequency emitting coil must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 1 and 5 are objected to because of the following informalities:
 - a. In regards to claim 1, the recitation “the spatial resolution in imaging of the biosample is not more than 1 tenth of a cell that forms the biosample” is indefinite since is not positively recited.
 - b. In regards to claim 5, the recitation “a stationary magnetic field generated by the magnet is not less than 11T, and more preferably not less than 14.1T, variation per hour

in Proton NMR frequencies due to variations in the stationary magnetic field is not more than 1Hz and the uniformity of the stationary field in the sample space is not more than 1Hz in Proton NMR frequencies" is indefinite since is not positively recited.

c. The recitation "growth conditions" in claim 9 is a relative term which renders the claim indefinite. The recitation "growth conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree or the conditions to be met for the intended purpose, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

d. The recitation "adequately controlled" in claim 9 is a relative term which renders the claim indefinite. The recitation "adequately controlled" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of what would be more appropriate to achieve the procedure and what conditions needs to be met in order to have said appropriated procedure as opposed to other optional procedures or variations of the procedure, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

e. The term "sufficient" in claim 9 is a relative term which renders the claim indefinite. The term " sufficient " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of the quality that renders the resolution to be sufficient for examination purposes, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant claims “the spatial resolution in imaging of the biosample is not more than one-tenth of a cell that forms the biosample.” There is not sufficient information in the specification in order for one of ordinary skill in the art to understand how to obtain the mathematical relation presented in the claim or if the mathematical expression is an arbitrary measurement.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.
9. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a

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gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: magnet, gradient coils, emitting coil, receiving coil and sample tube.

10. The term "high-quality" in claim 9 is a relative term which renders the claim indefinite. The term " high-quality " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 3, 5, 6, 9, 11, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US Patent 6,163,154 A) in view of Anderson (US Patent 5,552,709 A).

With respect to claim 1, Anderson '154 discloses a nuclear magnetic resonance imaging apparatus comprising a magnet (Figures 1-3, #1), a gradient magnetic field coil (Figure 15), a high frequency emitting coil, and a receiving coil (Figures 1-3, #13), wherein a biosample, including at least one of cells, organic tissues, and laboratory small animals, is inserted in a sample chamber (Abstract), the magnet is formed laterally divided split magnets, the direction of the magnetic field generated by said magnet is generally horizontal (Figures 1-3), the receiving

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coil is in the form of a solenoid coil, and the spatial resolution in imaging of the biosample is not more than one-tenth of a cell that forms the biosample (Abstract; Figures 1-3).

Anderson '154 discloses the claimed invention as stated above except for a sample chamber of generally 1 to 30 mm in diameter. However, Anderson '709 discloses a sample chamber of generally 1 to 30 mm in diameter (Column 8, lines 44 – 65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a sample chamber of generally 1 to 30 mm in diameter as shown by Anderson '709 with Anderson's ('154) NMR apparatus for the purpose of increasing the sensitivity at the magnetic field strengths (RF frequencies) use to study the sample using smaller volume cells as shown by Anderson '709.

13. With respect to claims 3, 5, 11 and 14, Anderson '154 discloses a nuclear magnetic resonance imaging apparatus wherein the imaging spatial is not more than 1 micron (abstract).

14. With respect to claims 6, 12 and 15, Anderson '154 discloses a nuclear magnetic resonance imaging apparatus wherein transmission of protein network information in the organic tissues can be imaged as two-dimensional or three-dimensional image formation (Figure 15).

15. With respect to claim 9, Anderson '154 discloses the MRI apparatus as stated above in claim 1, paragraph 13. It is to be notice that the method steps in lines 8-13; the method steps do not provide enough patentable weight since this claim is directed to an apparatus and since the courts have held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

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16. Claim 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US Patent 6,163,154 A) in view of Anderson (US Patent 5,552,709 A) and in further view of AAPA (Applicant admitted prior art).

With respect to claims 2 and 10, Anderson '154 and Anderson '709 disclose the claimed invention as stated above except for having a magnet system wherein the stationary magnetic field generated by the magnet is not less than 11T, and more preferably not less than 14.1T, variation per hour in Proton NMR frequencies due to variations in the stationary magnetic field is not more than 1Hz and the uniformity of the stationary field in the sample space is not more than 1Hz in Proton NMR frequencies. However, AAPA discloses stationary magnetic field generated by the magnet is not less than 11T, and more preferably not less than 14.1T, variation per hour in Proton NMR frequencies due to variations in the stationary magnetic field is not more than 1Hz and the uniformity of the stationary field in the sample space is not more than 1Hz in Proton NMR frequencies (Pages 1-8). There fore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a stationary magnetic field generated by the magnet of not less than 11T, and more preferably not less than 14.1T, variation per hour in Proton NMR frequencies due to variations in the stationary magnetic field is not more than 1Hz and the uniformity of the stationary field in the sample space is not more than 1Hz in Proton NMR frequencies as taught by AAPA with Anderson '154 and Anderson '709 nuclear magnetic resonance imaging apparatus for the purpose of having a magnet system that generates a strong and uniform magnetic field for MR examination.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1, 3, 5 and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 11 of copending Application No. 10/099,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent Application 10/099,978 claims the following: a nuclear magnetic resonance imaging apparatus comprising a magnet, a gradient magnetic field coil, a high frequency emitting coil, and a receiving coil, wherein a biosample, including at least one of cells, organic tissues, and laboratory small animals, is inserted in a sample chamber of

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generally 1 to 30 mm in diameter, the magnet is formed laterally divided split magnets, the direction of the magnetic field generated by said magnet is generally horizontal, the receiving coil is in the form of a solenoid coil, and the spatial resolution in imaging of the biosample is not more than one-tenth of a cell that forms the biosample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 12 of copending Application No. 10/326,085. Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent Application 10/326,085 claims the following: a nuclear magnetic resonance imaging apparatus comprising a magnet, a gradient magnetic field coil, a high frequency emitting coil, and a receiving coil, wherein a biosample, including at least one of cells, organic tissues, and laboratory small animals, is inserted in a sample chamber of generally 1 to 30 mm in diameter, the magnet is formed laterally divided split magnets, the direction of the magnetic field generated by said magnet is generally horizontal, the receiving coil is in the form of a solenoid coil, and the spatial resolution in imaging of the biosample is not more than one-tenth of a cell that forms the biosample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

20. Claims 4, 7, 8, 13, 16 and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

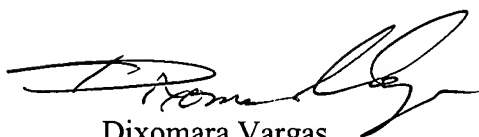
21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional prior art cited in the PTO 892 discloses MR spectroscopy systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dixomara Vargas whose telephone number is (571) 272-2252. The examiner can normally be reached on 8:00 am. to 4:30 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez can be reached on (571) 272-2245. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dixomara Vargas

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March 8, 2004



Diego Gutierrez

Supervisory Patent Examiner

Technology Center 2800